

OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

■ 1. The authority citation for part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 876.1310 to subpart B to read as follows:

§ 876.1310 Magnetically maneuvered capsule endoscopy system.

(a) *Identification.* A magnetically maneuvered capsule endoscopy system consists of an ingestible capsule and magnetic controller and is used for visualization of the stomach and duodenum. The ingestible capsule contains a camera that wirelessly captures images of the mucosa. The magnetic controller is used outside of the patient and is magnetically coupled with the capsule to control its location and viewing direction.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing with the device under anticipated conditions of use must evaluate visualization of the intended region and document the adverse event profile.

(2) Non-clinical testing data must demonstrate the optical, mechanical, and functional integrity of the device under physically stressed conditions. The following performance characteristics must be tested, and detailed protocols must be provided for each test:

(i) A bite test must be performed to ensure that the capsule can withstand extreme cases of biting;

(ii) A pH resistance test must be performed to evaluate integrity of the capsule when exposed to a physiological relevant range of pH values;

(iii) A battery life test must be performed to demonstrate that the

capsule's operating time is not constrained by the battery capacity;

(iv) A shelf life test must be performed to demonstrate that the device performs as intended at the proposed shelf life date;

(v) Optical testing must be performed to evaluate fundamental image quality characteristics such as resolution, field of view, depth of field, geometric distortion, signal to noise ratio, dynamic range, and image intensity uniformity;

(vi) A color performance test must be performed to compare the color differences between the input scene and output image;

(vii) A photobiological safety analysis must be performed based on maximum (worst-case) light exposure to internal gastrointestinal mucosa, and covering ultraviolet, visible, and near-infrared ranges, as appropriate. A mitigation analysis must be provided;

(viii) Performance testing must demonstrate that the viewing software clearly presents the current frame rate, which is either adjustable manually by the user or automatically by the device. Testing must demonstrate that the viewing software alerts the user when the video quality is reduced from nominal due to imaging data communication or computation problems;

(ix) A data transmission test must be performed to verify the robustness of the data transmission between the capsule and the receiver. This test must include controlled signal attenuation for simulating a non-ideal environment; and

(x) Magnetic field strength testing characterization must be performed to identify the distances from the magnet that are safe for patients and users with ferromagnetic implants, devices, or objects.

(3) Software validation, verification, and hazard analysis must be provided.

(4) Electrical safety, thermal safety, mechanical safety, and electromagnetic compatibility testing must be performed.

(5) The patient-contacting components of the device must be demonstrated to be biocompatible.

(6) Performance data must validate the reprocessing instructions for the reusable components of the device.

(7) Performance data must demonstrate the sterility of any device components labeled sterile.

(8) Human factors testing must demonstrate that the intended users can safely and correctly use the device, based solely on reading the instructions for use.

(9) Clinician labeling must include:

(i) Specific instructions and the clinical and technical expertise needed for the safe use of the device;

(ii) A detailed summary of the clinical testing pertinent to use of the device, including information on effectiveness and device- and procedure-related complications;

(iii) The patient preparation procedure;

(iv) A detailed summary of the device technical parameters;

(v) Magnetic field safe zones;

(vi) A screening checklist to ensure that all patients and operating staff are screened from bringing ferromagnetic implants, devices, or objects near the external magnet;

(vii) Reprocessing instructions for reusable components;

(viii) Shelf life for single use components; and

(ix) Use life for reusable components.

(10) Patient labeling must include:

(i) An explanation of the device and the mechanism of operation;

(ii) The patient preparation procedure;

(iii) A brief summary of the clinical study; and

(iv) A summary of the device- and procedure-related complications pertinent to use of the device.

Dated: April 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09735 Filed 5–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2022–N–0175]

Medical Devices; General and Plastic Surgery Devices; Classification of the Mountable Electromechanical Surgical System for Transluminal Approaches

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the mountable electromechanical surgical system for transluminal approaches into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the mountable electromechanical surgical system for transluminal approaches'

classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective May 6, 2022. The classification was applicable on February 26, 2021.

FOR FURTHER INFORMATION CONTACT:

Virag Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4609, Silver Spring, MD 20993-0002, 301-796-0452, Virag.Patel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the mountable electromechanical surgical system for transluminal approaches as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for

premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining "substantial equivalence"). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On April 17, 2019, FDA received Memic Innovative Surgery Ltd.'s request

for De Novo classification of the Hominis Surgical System. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on February 26, 2021, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 878.4961.¹ We have named the generic type of device mountable electromechanical surgical system for transluminal approaches, and it is identified as a software-controlled, patient bed- and/or operating table-mounted electromechanical surgical system with human/device interfaces that allows a qualified user to perform transluminal endoscopic or laparoscopic surgical procedures using surgical instruments attached to an electromechanical arm.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

¹ FDA notes that the "ACTION" caption for this final order is styled as "Final amendment; final order," rather than "Final order." Beginning in December 2019, this editorial change was made to indicate that the document "amends" the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

TABLE 1—MOUNTABLE ELECTROMECHANICAL SURGICAL SYSTEM FOR TRANSLUMINAL APPROACHES RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Thermal, electrical, or mechanical fault, or system malfunction resulting in tissue perforation or injury to patient or user.	Non-clinical performance testing; Electrical safety testing; Electromagnetic compatibility (EMC) testing; Software verification, validation, and hazard analysis; Human factors assessment; Clinical performance testing; Annual reporting; and Labeling.
Use error resulting in patient injury: • Dehiscence or delayed healing at the device access site. • Hemorrhage. • Thromboembolism. • Transluminal risks.	Non-clinical performance testing; Human factors assessment; Training; Clinical performance testing; Post-market surveillance; Annual reporting; Control on distribution; and Labeling.
Adverse tissue reaction	Biocompatibility evaluation, and Pyrogenicity testing.
Infection	Biocompatibility evaluation; Pyrogenicity testing; Sterilization validation; Reprocessing validation; Shelf-life testing; Clinical performance testing; and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

While this final order contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this final order. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 822, regarding postmarket surveillance of medical devices, have been approved under OMB control number 0910–0449; the collections of information in 21 CFR part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of

information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

- 1. The authority citation for part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

- 2. Add § 878.4961 to subpart E to read as follows:

§ 878.4961 Mountable electromechanical surgical system for transluminal approaches.

(a) *Identification.* A mountable electromechanical surgical system for transluminal approaches is a software-controlled, patient bed- and/or operating table-mounted electromechanical surgical system with human/device interfaces that allows a qualified user to perform transluminal endoscopic or laparoscopic surgical procedures using surgical instruments attached to an electromechanical arm.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The device manufacturer must develop, and update as necessary, a

device-specific use training program that ensures proper device setup/use/shutdown, accurate control of instruments to perform the intended surgical procedures, troubleshooting and handling during unexpected events or emergencies, and safe practices to mitigate use error.

(2) The device manufacturer may only distribute the device to facilities that implement and maintain the device-specific use training program and ensure that users of the device have completed the device-specific use training program.

(3) The device manufacturer must conduct and complete post-market surveillance, including an impact of the training program on user learning, behavior, and performance, in accordance with an FDA-agreed-upon protocol. The device manufacturer must submit post-market surveillance reports that contain current data and findings in accordance with the FDA-agreed-upon protocol.

(4) The device manufacturer must submit a report to FDA annually on the anniversary of initial marketing authorization for the device, until such time as FDA may terminate such reporting, which comprises the following information:

(i) Cumulative summary, by year, of complaints and adverse events since date of initial marketing authorization; and

(ii) Identification and rationale for changes made to the device, labeling or device-specific use training program, which did not require submission of a premarket notification during the reporting period.

(5) Labeling must include:

(i) A detailed summary of clinical performance testing conducted with the device, including study population, results, adverse events, and comparisons to any comparator groups identified;

(ii) A statement in the labeling that the safety and effectiveness of the device has not been evaluated for outcomes related to the treatment or prevention of cancer, including but not limited to risk reduction, overall survival, disease-free survival and local recurrence, unless FDA determines that it can be removed or modified based on clinical performance data submitted to FDA;

(iii) Identification of compatible devices;

(iv) The list of surgical procedures for which the device has been determined to be safe with clinical justification;

(v) Reprocessing instructions for reusable components;

(vi) A shelf life for any sterile components;

(vii) A description of the device-specific use training program;

(viii) A statement that the device is only for distribution to facilities that implement and maintain the device-specific use training program and ensure that users of the device have completed the device-specific use training program; and

(ix) A detailed summary of the post-market surveillance data collected under paragraph (b)(3) of this section and any necessary modifications to the labeling to accurately reflect outcomes based upon the post-market surveillance data collected under paragraph (b)(3) of this section.

(6) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use.

(7) Human factors validation testing must be performed and must demonstrate that the user interfaces of the system support safe use in an operating room environment.

(8) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and must include:

(i) Device motion accuracy and precision;

(ii) System testing;

(iii) Instrument reliability;

(iv) Thermal effects on tissue;

(v) Human-device interface;

(vi) Mounting hardware testing;

(vii) Workspace access testing; and

(viii) Performance testing with

compatible devices.

(9) Software verification, validation, and hazard analysis must be performed. Software documentation must include an assessment of the impact of threats and vulnerabilities on device functionality and end users/patients as part of cybersecurity review.

(10) Electromagnetic compatibility and electrical, thermal, and mechanical safety testing must be performed.

(11) Performance data must demonstrate the sterility of all patient-contacting device components.

(12) Performance data must support the shelf life of the device components provided sterile by demonstrating continued sterility and package integrity over the labeled shelf life.

(13) Performance data must validate the reprocessing instructions for the reusable components of the device.

(14) Performance data must demonstrate that all patient-contacting components of the device are biocompatible.

(15) Performance data must demonstrate that all patient-contacting components of the device are non-pyrogenic.

Dated: April 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09749 Filed 5–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2022–0227]

Special Local Regulation; Crystal Pier Outrigger Race, San Diego, CA

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the Crystal Pier Outrigger Race special local regulations on the waters of Mission Bay, California, on May 7, 2022. These special local regulations are necessary to provide for the safety of the participants, crew, spectators, sponsor vessels, and general users of the waterway. During the enforcement period, persons and vessels are prohibited from anchoring, blocking, loitering, or impeding within this regulated area unless authorized by the Captain of the Port, or his designated representative.

DATES: The regulations in 33 CFR 100.1101 will be enforced from 7 a.m. through 5 p.m. on May 7, 2022, for the locations described in Item No. 14 in Table 1 to § 100.1101.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander John Santorum, Waterways Management, U.S. Coast Guard Sector San Diego, CA;

telephone 619–278–7656, email MarineEventsSD@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulations in 33 CFR 100.1101 for the Crystal Pier Outrigger Race in Mission Bay, CA in 33 CFR 100.1101, for the locations described in Item No. 14 in Table 1 to that section from 7 a.m. until 5 p.m. on May 7, 2022. This enforcement action is being taken to provide for the safety of life on navigable waterways during the event. The Coast Guard's regulation for recurring marine events in the San Diego Captain of the Port Zone identifies the regulated entities and area for this event. Under the provisions of 33 CFR 100.1101, persons and vessels are prohibited from anchoring, blocking, loitering, or impeding within this regulated area, unless authorized by the Captain of the Port, or his designated representative. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

In addition to this document in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via the Local Notice to Mariners, marine information broadcasts, and local advertising by the event sponsor.

If the Captain of the Port Sector San Diego or his designated representative determines that the regulated area need not be enforced for the full duration stated on this document, he or she may use a Broadcast Notice to Mariners or other communications coordinated with the event sponsor to grant general permission to enter the regulated area.

Dated: May 2, 2022.

T.J. Barelli,

Captain, U.S. Coast Guard, Captain of the Port San Diego.

[FR Doc. 2022–09722 Filed 5–5–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0190]

RIN 1625–AA00

Safety Zone; Sabine River, Orange, TX

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain navigable waters of the Sabine